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100718-283
6713-Dr. Wi-ar

REMARKS

Amendment to the Claims

35 U.S.C. 112, second paragraph rejections

Claims 9 and 18 have been amended in the manner suggested by the examiner. (For future record, it is believed that the amendment to claim 18 does not alter the scope of the original claim as it clearly indicates that the examiner recognized the concept that an encapsulated form can take place in a solution form, e.g. as in liposomes or micelles).

35 U.S.C. 103(a) rejection

- (1) Claims 8, 9 and 19-21 were rejected by the examiner as being obvious over Caserio et al. (U.S. Patent 4,664,910). Applicants reserve the right to pursue this broader subject matter in a divisional application. It is believed that this rejection is rendered moot with the addition of the limitation of previous claim 16 into claim 8.
- (2) Claims 16-18 were rejected by the examiner as being obvious over Caserio et al., *ibid.* (as applied to claims 8, 9 and 19-21) in view of Tisdale et al. (U.S. Patent 6,103,246).

Caserio reference

The examiner relies in *In re Aller* to support two of her suppositions.

The first supposition is that one of ordinary skill in the art would have discovered the optimum ranges claimed by the applicants with respect to bile acids because Caserio et al. teaches a general range for cholanolic acids which encompasses the claimed range. However, the ranges for cholanolic acid in Caserio et al. was for a different purpose than what is claimed here, i.e. Caserio et al. generically refers to a liquid form of their product whereas the currently amended claims are directed toward bile acids which have been encapsulated. As such, there is now a clear disconnect for the argument of routine optimization, i.e. routine optimization of the cholanolic acid ranges of Caserio et al. would not result in the encapsulated compositions claimed by the applicants.

While there may have been at least an arguable basis for applying *Aller* in the context of cholanolic acid, there was no basis for applying the *Aller* standard to the anti-oxidant limitation. The very next section of the MPEP after *Aller* has been disclosed is MPEP 2144.05 section II (Optimization of Ranges) states that "A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. [citation omitted]." There is no indication that the Caserio et al. reference recognized anti-oxidants as being a results effective variable within the context of their invention which was directed toward drying the skin or cleaning the grease of the skin due to excessive sebum or sweat (see col. 4, lines 63-68).

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The examiner also points out that it is possible that the cholanic acid ranges of Caserio et al. meet the applicants claimed bile salt ranges with respect to the phrase "a barrier strength effective amount".

However, the only claim that uses the "a barrier strength effective amount" is claim 20 which is a method of use claim. There is no indication from Caserio et al. that the invention of Caserio et al. strengthened the barrier function of the skin. While the applicants are arguing that the claimed preparations are unobvious over the prior art, even if the preparation were identical to the prior art, this would not preclude the applicants claiming a new use for an old composition (An invention based upon the discovery of an unobvious use of an old composition must be claimed in a method or process claim, not product claims. see *In re Moreton*, 288 F.2d 708, 129 USPQ 227 (CCPA 1961)).

Establishing a *prima facie* case of obviousness is a legal determination based on underlying factual determinations. If there are factual reasons why compositions to dry or clean the skin would be considered to be equivalent to strengthening the barrier function of the skin, they have not been presented.

With respect to the method of use claims, the examiner cites *In re Spada* to support her position. MPEP 2144.04 states that "...if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court." However, *Spada* fails this standard on several levels.

First, all of the claims in *Spada* were composition claims which is not the case here. In fact the decision specifically confirmed that *Spada* had a right to claim the process - "All of *Spada*'s claims are composition claims. The issue is not before us of whether *Spada* may have discovered a new use of a known composition, which use may be patentable as a process. 35 U.S.C. §101. see *In re Hack*, 44 CCPA 954, 245 F.2d 246, 248, 114 USPQ 161, 163 (1957)."

Second, the issue in *Spada* was not obviousness of the composition but anticipation, i.e. "Products of *identical* chemical composition cannot have mutually exclusive properties." see *In re Papesch*, 50 CCPA 1084, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963). Again, this is not the issue here.

Lastly, as acknowledged by the examiner and indicated above, it is the identical nature of the composition which is important. However, commonality of a single component is not the same being an "identical chemical composition" (especially after the amendment which requires that the bile salt be encapsulated), a fact which the examiner appeared to recognize as no rejection under 102 was made.

Caserio in view of Tisdale

As Tisdale is primarily relied upon for their teachings of liposomes, the Tisdale reference does not fully address the deficiencies of the Caserio et al. reference outlined above. However, even if Caserio et al. was an appropriate reference for combination with Tisdale et al. there is insufficient motivation and a reliance on hindsight reconstruction in order to arrive at the applicants' claimed invention.

Determinations of obviousness requires that the references be viewed by what one of ordinary

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skill in the art would have thought to be obvious: (1) at the time the invention was made; and (2) without the benefit of the applicants' claim before them. The ruling on obviousness in *In re Fine* closely adheres to the position maintained by the applicants and is reproduced in part below:

"Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). But it 'cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And 'teachings of references can be combined *only* if there is some suggestion or incentive to do so.' *Id.* Here the prior art contains none.

Instead, the Examiner relies on hindsight in reaching his obviousness determination...

It is essential that 'the decisionmaker forget what he or she has been taught at trial about the claimed invention **and cast the mind back to the time the invention was made...**to occupy the mind of one skilled in the art **who is presented only with the references**, and who is normally guided by the then-accepted wisdom in the art.' *Id.* One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention."

see *In re Fine*, 5 USPQ2d 1596, 1599, 1600 (Fed. Cir. 1988).

In *Texas Instruments Inc.* (relying on *Fine*) it was further stated that "[a]bsent such suggestion to combine the references, respondents can do no more than piece the invention together using the patented invention as a template. Such hindsight reasoning is impermissible." see *Texas Instruments Inc. v. International Trade Commission*, 26 USPQ2d 1018, 1029 (Fed. Cir. 1993).

Applying these rulings to the present facts at hand, the question becomes:

"As of 20 July 1999 (the 371 date of this application), what would have motivated one of ordinary skill in the art to modify the teachings of Caserio et al. to arrive at the presently claimed invention when not having the luxury of the applicants claims to provide them with any guidance as to how to modify Caserio et al.'s teachings?"

While Tisdale et al. teaches a liposome, Caserio et al. provides no such direction with regard to their invention with respect to additional components or forms of their invention thereof. Without such direction, one of ordinary skill in the art has a virtually limitless number of permutations by which the Caserio et al. reference could be modified. *In re Rice*, 178 USPQ 478, (CCPA 1973) offers additional guidance on this point, "...the board said, referring to the appellant's ingredients, 'It should be noted that an infinite number of combinations is possible.' Accepting that as an approximation to the truth, we fail to see the obviousness in devising appellant's...[invention] as claimed." *Id.* at 480.

Moreover, MPEP 2143.01 states that "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the

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teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).") In the present situation, the examiner notes that Tisdale et al. teaches that their liposomes "...deliver their active agents in a time-release action." This would appear to be contrary to the intended use of Caserio et al., i.e. the practitioner would want immediate removal of excessive moisture or grease due to an accumulation of sebum and/or sweat. While the motivation to combine need not match the intended use of the applicants' invention, it would appear that one of ordinary skill in the art would be directed away, not towards, using liposomes in the invention of Caserio et al.

Therefore, for any of the above reasons, it is believed that the Caserio et al. and Tisdale et al. references do not render the applicants' invention to be obvious.

Claims 22 and 23 were rejected by the examiner over Caserio et al. in view of Pittrof et al. (U.S. Patent 5,376,646).

Pittrof et al. is primarily relied upon for their teachings of liposomes, the Tisdale reference does not fully address the deficiencies of the Caserio et al. reference outlined above. However, even if Caserio et al. was an appropriate reference for combination with Tisdale et al. there is insufficient motivation and a reliance on hindsight reconstruction in order to arrive at the applicants' claimed invention.

The standard for review which were established above in the arguments against Caserio et al. in view of Tisdale et al. are also applicable here, i.e. given the infinite number of possible modifications for Caserio et al. (and in this case the infinite numbers of selections from within Tisdale et al.; also note that Tisdale et al. teaches mixed micelles), there is no direction or suggestion to make the appropriate modification without relying on the applicants' claims as a template.

Closing

Applicants also believe that this application is in condition for allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Respectfully submitted,
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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.111 is being facsimile transmitted to the United States Patent and Trademark Office on the date indicated below:

Date: 7 November 2003

By: Agata Glinska
Agata Glinska